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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	. ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,305	10/24/2003	William F. Crismore	7404-572/BMID-9738RE-DIV3 1452	
41577 WOODARD	7590 01/14/2009 FMHARDT MORIARTY	Y, MCNETT & HENRY LLP	EXAMINER	
111 MONUM	ENT CIRCLE, SUITE 37	ALEXANDER, LYLE		
INDIANAPOLIS, IN 46204-5137			ART UNIT	PAPER NUMBER
			1797	
•		,	NOTIFICATION DATE	DELIVERY MODE
			01/14/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@uspatent.com GMercer@uspatent.com Karla.Dirks@Roche.com

	Application No.	Applicant(s)				
	10/693,305	CRISMORE ET AL.				
Office Action Summary	Examiner	Art Unit				
	Lyle A. Alexander	1797				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period way reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
	Responsive to communic at an(s) filed on <u>21 December 2007</u> .					
,	·					
,) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
 4) Claim(s) 104,107,109-113,115-117 and 127-134 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 104, 107, 109-113, 115-117, 127-134 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 						
Application Papers						
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomposed and all accomposed are specified and any objection to the Replacement drawing sheet(s) including the correct and the specified are specified to by the Examine and the specified are specified as a sp	epted or b) objected to by the drawing(s) be held in abeyance. Se ion is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal R 6) Other:	ate				

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 104, 107, 109-113, 115-117 and 127-130 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claims 104 and 127 contain limitations directed to "opaque portions" which are not taught in the original disclosure. Applicants reference column 8 lines 27-29 as supporting the limitations of an opaque portion. The Office has considered this portion of the specification and notes there is no explicit teaching the entire surface (16) is opaque. Rather, the opaque ink described in the specification in the pattern (27) could be printed instructions or other printed matter on the surface (16). It is not clear that one having ordinary skill in the art could conclude from this portion of the specification the entire surface (16) is opaque.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite as to the positioning of the opaque portion with respect to the remainder of the strip (e.g. is the remainder of the strip opaque except for the viewing area?).

Reissue Applications

The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Applicants' have not specifically identified the support in the original specification for the 9/29/08 amended claims. Applicants' 12/21/07 statements do not identify support in the original specification for the 9/29/08 amendments.

The reissue of h/declaration filed with this application is defective because it fails to contain the statement required under 37 CFR 1.175(a)(1) as to applicant's belief that the original patent is wholly or partly inoperative or invalid. See 37 CFR 1.175(a)(1) and see MPEP § 1414. The reissue declaration filed on 12/21/07 is not signed by all of the inventors.

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Claims 104, 107, 109-113, 115-117, 127-134 are rejected as being based upon a defective reissue oath under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 131-134 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Applicants' disclosure of "Glucose Elite" as characterized in the 12/12/06 remarks.

See the appropriate paragraph of the 6/25/07 Office action.

These claims as of the 9/29/08 amendments do not have any limitations to opaque areas and are clearly anticipated by the cited prior art.

Response to Arguments

Applicant's arguments filed 12/21/07 have been fully considered but they are not persuasive.

Applicants state the cited prior art, "Glucose Elite", fails to teach an opaque portion of the test device. The Office agrees with Applicants' remarks. However, the Office does not believe there is support in the original disclosure for an opaque portion as claimed and has rejected the claims under 35 USC 112 1st paragraph. Claims 131-134 do not require an opaque portion and have been properly read on the cited prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is

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571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander Primary Examiner Art Unit 1797

/Lyle A Alexander/ Primary Examiner, Art Unit 1797